

EXH (B)

United States Court of Appeals for the Federal Circuit

93-1076

NORTH AMERICAN VACCINE, INC. and  
NATIONAL RESEARCH COUNCIL OF CANADA,

Plaintiffs-Appellants,

v.

AMERICAN CYANAMID COMPANY and  
PRAXIS BIOLOGICS, INC.,

Defendants-Appellees.

Stephen R. Smith, Morgan & Finnegan, of New York, New York, argued for plaintiffs-appellants. With him on the brief were John A. Diaz and Arnold I. Rady. Also on the brief were Mark J. Abate, Tony V. Pezzano and Bruce D. Radin, of counsel.

Donald R. Dunner, Finnegan, Henderson, Farabow, Garrett & Dunner, of Washington, D.C., argued for defendants-appellees. With him on the brief were Brian G. Brunsvold, Thomas H. Jenkins and Thomas W. Banks. Of counsel was Daniel J. Thomasch, Donovan, Leisure, Newton & Irvine.

Appealed from: U.S. District Court  
Southern District of New York

Judge Griesa

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DECIDED: October 6, 1993

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Before LOURIE, Circuit Judge, SKELTON, Senior Circuit Judge, and  
RADER, Circuit Judge.

LOURIE, Circuit Judge.

National Research Council of Canada and its exclusive licensee, North American Vaccine (collectively NRC), appeal from the judgment of the United States District Court for the Southern District of New York holding claims 12 and 25 of U.S. Patent 4,356,170 invalid for indefiniteness under 35 U.S.C. § 112, ¶ 2 (1988), and not infringed by American Cyanamid Co. and Praxis Biologics, Inc. (collectively Cyanamid). North American Vaccine, Inc. v. American Cyanamid Co., 24 USPQ2d 1898 (S.D.N.Y. 1992). We affirm-in-part and reverse-in-part.

BACKGROUND

On February 28, 1991, NRC brought an action against Cyanamid alleging infringement of the '170 patent. That patent, entitled

"Immunogenic Polysaccharide-Protein Conjugates," relates to human infant vaccines against bacterial infections such as meningitis. The principal components of the vaccines are polysaccharide-protein conjugates. The polysaccharide, which is derived from the bacteria against which immunization is sought, has antigenic properties that elicit an immune response. Infant immune systems, however, do not respond well to the polysaccharide unless it is linked to a protein.

While linking of the polysaccharide and protein enhances infants' immune response to the antigenic polysaccharide, the immune response is hampered by "crosslinking." The parties indicate that crosslinking obstructs the antigenic sites of the polysaccharide, precluding an effective immune response. The amount of crosslinking increases with the number of proteins that are linked to the polysaccharide. The claimed invention purports to avoid the problem associated with crosslinking by linking the protein only to a terminal portion of the polysaccharide, thereby preserving the antigenic properties of the polysaccharide and producing an immune response in infants. The meaning of the expression "a terminal portion" in the claims is a key issue in this case. The meaning of the term "crosslinking" is also contested.

Trial was limited to the issues of infringement and validity of claims 12 and 25, which are directed, respectively, to a polysaccharide-protein conjugate and a human infant vaccine

comprising that conjugate. Both are dependent upon claim 11, which reads:

11. An antigenic-polysaccharide-protein conjugate wherein the polysaccharide and protein are covalently linked through a

CH<sub>2</sub>-NH-protein

linkage to a terminal portion of the polysaccharide without significant crosslinking, said antigenic polysaccharide having a MW [molecular weight] above about 2,000.

(emphasis added). Claims 12 and 25 read as follows:

12. The conjugate of claim 11 wherein the antigenic polysaccharide is selected from the group derived from meningococci, Haemophilus influenza, pneumococci, beta-hemolytic streptococci, and E. coli.

25. A human infant vaccine comprising the conjugate of claim 11 wherein the polysaccharide comprises at least one of meningococcal polysaccharide and Haemophilus influenza polysaccharide.

(emphases added).

A polysaccharide is a sugar molecule having a carbon backbone with hydroxy groups attached, to which proteins may be linked. Linking a protein to a polysaccharide generally involves modifying the hydroxy groups to create one or more active sites and covalently linking the activated polysaccharide to a free amino group of a protein. The result is a polysaccharide-protein conjugate.

Cyanamid's accused product, "HibTITER," is a vaccine against Haemophilus influenza (H. flu) type b (Hib) bacteria that can cause

meningitis. HibTITER consists of Hib polysaccharides linked to one or more proteins. Specifically, it is comprised of three components referred to as "monomers," "dimers," and "trimers." Monomers, which constitute 50% of the polysaccharide-protein molecules of HibTITER, consist of a single protein linked to a terminal end of one or more polysaccharides; dimers consist of two proteins linked together by polysaccharide; and trimers consist of three proteins linked together by polysaccharides. The protein linkage in each of these components is at a terminal portion of the Hib polysaccharide; none has a protein linkage along the backbone of the polysaccharide. Monomers, having a protein linkage at only one terminal, are referred to as monofunctional. Dimers and trimers, having linkages at both terminals of the polysaccharide, are referred to as difunctional and exhibit what has been called end-to-end crosslinking.

The district court entered judgment for Cyanamid, holding that claims 12 and 25 were not infringed and were invalid for indefiniteness under 35 U.S.C. § 112, second paragraph. NRC appeals from that judgment.

#### DISCUSSION

##### A. Infringement

A determination of patent infringement requires a two-step analysis. First, a claim must be interpreted to determine its proper scope and meaning; second, it must be determined whether an accused device is within the scope of the properly interpreted

claim. ZMI Corp. v. Cardiac Resuscitator Corp., 844 F.2d 1576, 1578, 6 USPQ2d 1557, 1559 (Fed. Cir. 1988). The first step is an issue of law and the second a question of fact. Minnesota Mining & Mfg., Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1570, 24 USPQ2d 1321, 1330 (Fed. Cir. 1992) (citations omitted). A determination of literal infringement requires that each limitation in the asserted claims be present in the accused device. Hi-Life Products, Inc. v. American Nat'l Water-Mattress Corp., 842 F.2d 323, 325, 6 USPQ2d 1132, 1133 (Fed. Cir. 1988). Only the issue of literal infringement is before us in this case.

Whether HibTITER, which includes monomers, dimers, and trimers, infringes claims 12 and 25, turns on our interpretation of the limitation "linkage to a terminal portion of the polysaccharide without significant crosslinking" in claim 11. It is not disputed that the monomer components in HibTITER meet this limitation. Thus, if, contrary to what the district court decided,<sup>1/</sup> the monomers themselves meet all the other limitations of the claims, including being a conjugate, infringement of the claims would be established because they contain "linkage to a terminal portion of the polysaccharide without significant crosslinking" and they are quantitatively a significant component of the product. However, at oral argument, counsel for NRC stated

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<sup>1/</sup> The court rejected NRC's argument that infringement is established on the basis of the monomers alone. NRC had asserted that "conjugate" in claim 11 referred to an individual molecule and that HibTITER infringed since each monomer molecule was within the scope of the asserted claims.

that NRC is not contesting this aspect of the court's decision.<sup>2/</sup> The only issue before us, therefore, is whether the other components of the vaccine, the dimers and trimers which have protein linkages at both terminal portions of the Hib polysaccharides and exhibit end-to-end crosslinking, come within

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<sup>2/</sup> At oral argument, Judge Lourie asked counsel for NRC about the meaning of the word "conjugate" in the claims. Counsel for NRC responded:

Well, the word "conjugate" was in dispute at trial, and my brother Mr. Dunner has made an issue of it on appeal, but it is really not an issue because we are not contesting the district court's interpretation of the word conjugate. The district court interpreted the word "conjugate" as embracing all the molecules in the mixture and therefore and [sic] the accused product really has three types of molecules. It has so-called monomers, which have no cross-linking, and it has dimers and trimers which have the end-to-end cross-linking. And we have an argument below that the monomers should infringe irrespective of the dimers and trimers. And the district court rejected that because he said, "no, the word conjugate embraces the entire mixture." But, we are not contesting that on our primary argument on appeal. Our primary argument on appeal is that not only the monomers with no cross-linking, but the dimers and the trimers, which have only end-to-end cross-linking, meet all the limitations of the claims. They have a linkage to a terminal portion without significant cross-linking. And therefore, when the claims are properly construed, then all the molecules in the entire product meet the limitations of the claim, irrespective of whether conjugate means a single molecule or all the molecules. So I don't think conjugate is really an issue on this appeal, your Honor.

Transcript from oral argument (emphases added).

the meaning of the above-quoted language, in which case the totality of the accused product would be infringing.

The district court construed this phrase as being limited to linkage at only one terminal portion of the polysaccharide, excluding all crosslinking, even end-to-end crosslinking. Accordingly, the court held that the claims did not cover the dimers and trimers in HibTITER. NRC argues that the court's claim interpretation was erroneous and that the limitation requiring "linkage to a terminal portion of the polysaccharide without significant crosslinking" in claim 11 is not limited to linkage at only a single terminal, but includes linkages at either one or both terminals of the polysaccharide. According to NRC, end-to-end crosslinking which involves linkages at both terminal portions of the polysaccharide is not "significant crosslinking" for purposes of the asserted claims since it achieves the intended purpose of the invention by avoiding crosslinking along the backbone of the polysaccharide. NRC also argues that the inclusion of references to Haemophilus influenza in dependent claim 12 and the specification indicate that claim 11 was intended to be interpreted to include end-to-end crosslinking because polysaccharides from that organism lead to end-to-end crosslinking. Thus, NRC asserts, the properly interpreted claims cover the dimers and trimers in HibTITER. We disagree and conclude that the contested phrase does not include polysaccharide-protein linkages at both terminal portions of the polysaccharide.

A determination as to the scope and meaning of a claim is a question of law which we review de novo. ZMI, 844 F.2d at 1578, 6 USPQ2d at 1559. Therefore, we need not defer to the district court's claim interpretation. Specialty Composites v. Cabot Corp., 845 F.2d 981, 986, 6 USPQ2d 1601, 1604 (Fed. Cir. 1988) (citation omitted). Cyanamid characterizes these issues as questions of fact, imposing on us a "clearly erroneous" standard of review. It argues that the meaning of claim language raises factual questions. We agree that a genuine evidentiary conflict underlying the meaning of claim terms raises a question of fact, but the questions before us in this case go to the heart of what the claims mean. Resolution of disputed issues regarding the meaning of contested language is ultimately a determination of what claims mean and what they cover. It is a matter of law for this court to decide without special deference to the district court. Absent "a genuine evidentiary conflict created by the underlying probative evidence pertinent to the claim's interpretation[,] . . . claim interpretation may be resolved as an issue of law by the court taking into account the specification, prosecution history or other evidence . . . ." Johnston v. IVAC Corp., 885 F.2d 1574, 1579-80, 12 USPQ2d 1382, 1386 (Fed. Cir. 1989) (citations omitted).

In construing claims, we begin with the language of the claims themselves. SmithKline Diagnostics, Inc. v. Helena Lab., Corp., 859 F.2d 878, 882, 8 USPQ2d 1468, 1472 (Fed. Cir. 1988) (citations omitted). Claim 11 specifically refers to "a terminal portion";

it does not refer to "any terminal portion" or to "all terminal portions." While it is generally accepted in patent parlance that "a" can mean one or more, see Robert C. Faber, Landis on Mechanics of Patent Claim Drafting 531 (3d ed. 1990) ("In a claim, the indefinite article A or AN connotes 'one or more.'"), there is no indication in the patent specification that the inventors here intended it to have other than its normal singular meaning.

When the meaning of a claim term is in doubt, we look to the specification for guidance. See Hormone Research Foundation, Inc. v. Genentech, Inc., 904 F.2d 1558, 1562, 15 USPQ2d 1039, 1042 (Fed. Cir. 1990), cert. dismissed, 111 S. Ct. 1434 (1991). In doing so here, we find no indication in the patent specification that the inventors intended to include end-to-end linkages within the scope of their invention. All references to polysaccharide linkages speak of a linkage, not multiple linkages. For example, the summary of the invention describes the formation of the protein linkage to a terminal portion of the polysaccharide as follows:

We have found it possible to introduce a free aldehyde group into the polysaccharide molecule in a terminal location and to specifically couple this aldehyde group to protein without activating other functional groups on the polysaccharide.

Col. 2, lines 33-37 (emphases added.) Similarly, the specification states:

The reductive amination covalently couples the terminal aldehyde group of the polysaccharide to a free amino group on the protein through a -CH<sub>2</sub>-NH-protein linkage where the -CH<sub>2</sub>- derives from the aldehyde group. There is no

significant cross-linking by this method . .

Col. 3, lines 55-64 (emphases added.) Reference to "the" terminal aldehyde group is consistent with linkage at only one terminal, not at both.

The examples in the specification also support linkage at only one terminal. In teaching the selective periodate oxidation of meningococcal polysaccharide, the specification states that "[t]he oxidized polysaccharides now had a terminally-located aldehyde group." Col. 5, lines 14-15. Use of the term "a" and reference to "group" in the singular shows that the specification teaches linkage at only one terminal portion. Furthermore, in teaching the direct conjugation of the oxidized polysaccharides with proteins, the specification states:

It is unlikely that the reducing terminal sialic acid residue at the opposite end would oxidize to any great extent using these conditions because it exists in solution mainly in its pyranose ring form and such has been found to behave similarly to an interchain residue.

Col. 5, lines 50-54 (emphasis added.) This statement shows that it is "unlikely" to obtain linkage at both terminals. Similarly, with respect to meningococcal group A polysaccharide, the specification teaches:

[T]he reducing end-group N-acetyl-mannosamine residue was made into the most susceptible residue by simply reducing it to its open chain N-acetylmannosaminitol derivative. In this form, the modified group A polysaccharide was selectively oxidized at this residue to generate a terminally-located aldehyde group.

Col. 5, line 67 - col. 6, line 5 (emphases added.) Again, reference to "the" reducing end group, "this" residue, and "a" terminal aldehyde are consistent with linkage in the singular.

NRC argues that the "significant crosslinking" that the inventors intended to avoid was not end-to-end crosslinking, but crosslinking across the backbone of the polysaccharide molecule. While such an interpretation might make sense as a theoretical concept, it has no support in the specification. The word "backbone" does not appear in the specification, nor does the concept of avoiding linking other than at multiple terminal portions. Contrary to NRC's argument that "significant crosslinking" is crosslinking along the backbone of the polysaccharide, the specification states:

The reductive amination covalently couples the terminal aldehyde group of the polysaccharide to a free amino group on the protein . . . . There is no significant cross-linking by this method . . . .

Col. 3, lines 55-64 (emphases added.) The above-referenced statement that linkage to the terminal portion results in "no significant crosslinking" shows that "significant crosslinking" for purposes of the claims was not intended to mean linking along the backbone as NRC urges, but linking at more than one terminal.

It is the responsibility of patent applicants to disclose their inventions adequately. 35 U.S.C. §112. There is no such disclosure of the concept of avoiding crosslinking along the backbone in this patent. Thus, an invention of that breadth does

not meet the description requirement. See Carmen Industries, Inc. v. Wahl, 724 F.2d 932, 937 n.5, 220 USPQ 481, 485 n.5 (Fed. Cir. 1983) ("Claims should be so construed, if possible, as to sustain their validity.") (citations omitted). As explained above, the examples are consistent with monofunctionality, not difunctionality. A patent applicant cannot disclose and claim an invention narrowly and then, in the course of an infringement suit, argue effectively that the claims should be construed to cover that which is neither described nor enabled in the patent. One of the inventors, Dr. Jennings, testified that he intended to include difunctional molecules within the scope of his invention. Such after-the-fact testimony is of little weight compared to the clear import of the patent disclosure itself. See Senmed, Inc. v. Richard-Allen Medical Indus. Inc., 888 F.2d 815, 819 n.8, 12 USPQ2d 1508, 1512 n.8 (Fed. Cir. 1989) (Where meaning of claim term is clear from specification and prosecution history, the inventor's "self-serving post-hoc opinion testimony on the legal question [] whether it should have a different meaning was of little if any significance.") (citation omitted)).

NRC argues that inclusion of the words Haemophilus influenza in the dependent claims and specification prove that difunctional molecules are within the scope of claim 11 because such organisms lead to difunctional products according to this invention. While it is true that dependent claims can aid in interpreting the scope of claims from which they depend, they are only an aid to

interpretation and are not conclusive. The dependent claim tail cannot wag the independent claim dog. Certainly in this case, as we have indicated, there is no further disclosure or description in the specification of difunctional molecules resulting from H. flu or any other organism. Moreover, the district court did not find that H. flu always yields a difunctional result, as NRC asserts, but found that one of the "five or six" H. flu serotypes "is the one which yields the difunctional result." 24 USPQ2d at 1903.

There also was evidence at trial contrary to NRC's assertion that use of H. flu always results in difunctionality. Dr. Eby, one of Cyanamid's expert witnesses, testified that the H. flu polysaccharide could be treated to create only a single aldehyde that would result in monofunctionality and that such monofunctional H. flu polysaccharides could have been made by one skilled in the art in 1981 when the patent application was filed. Dr. Eby explained that the reference to H. flu in claim 12 is completely consistent with monofunctionality, thereby providing a basis for its inclusion consistent with the otherwise clear singular meaning of "a terminal portion." Thus, use of the words Haemophilus Influenza in claims 12 and 25 is not inconsistent with a monofunctional interpretation of claim 11.

Finally, if we were to interpret claim 11 on the basis of NRC's argument concerning what claim 12 requires, claim 11 would include polyfunctional molecules, which are concededly not within

the scope of the invention. That cannot be what NRC intends. We therefore conclude that "linkage to a terminal portion" includes linkage only to "a terminal portion" at one end of the polysaccharide.

Since we have interpreted the expression "a terminal portion" to include only monofunctionality, it is clear that the limitation "without significant crosslinking" excludes from the claims linkage other than monofunctional linkage. End-to-end crosslinking, consisting of protein linkages at both terminal portions of a polysaccharide, is inconsistent with the clear meaning of the expression "a terminal portion." Thus, end-to-end crosslinking is "significant crosslinking" in terms of this patent and it is excluded from the claims. As noted earlier, the specification does not use the term end-to-end crosslinking or difunctionality, nor does it use any language which conveys that backbone crosslinking was excluded, but end-to-end crosslinking was not. As for the term "significant," it is undisputed that 50% of the polysaccharide-protein molecules are other than monofunctional, that they have end-to-end crosslinking. There is no basis for concluding that 50% is not significant. Finally, it is the responsibility of patent applicants to define their inventions adequately. In the absence of any definition of this term in the specification, NRC cannot complain if its after-the-fact definition is not accepted. Thus, the district court correctly construed the claim in concluding that end-to-end crosslinking did not meet the limitations of the claims.

Cyanamid, as did the district court, emphasizes an article and speech of Dr. Jennings, one of the named inventors on the patent, in which he described his research on polysaccharide-protein conjugates as directed toward achieving monofunctionality. Jennings made these presentations at about the same time as he filed his patent application. The court concluded that Jennings' failure to clearly express in his application his intention to claim more than the monofunctional product of his earlier work showed that the claims were limited to the scope of his earlier work. 24 USPQ2d at 1902.

Cyanamid argued before us that the court correctly concluded that the monofunctional approach embodied in Jennings earlier work was carried over into his patent. According to Cyanamid, Jennings' article and speech show the "evolution" of the patent and compel a claim construction to require monofunctionality. While we have affirmed the district court's interpretation of the claims, we must reject its doing so on the basis of this argument. A patent is to be interpreted by what it states rather than by what the inventor wrote in a scientific publication.

There is no inconsistency between writing a paper (or giving a speech) on a particular embodiment of an invention and then claiming one's invention more broadly in a patent application. Patents often teach embodiments not carried out in the laboratory; scientific papers rarely do. Thus, it was error, albeit harmless error, for the district court to conclude that the narrow scope

of the article limits the scope of the patent claims, which should be judged on their own merits.

Having construed the claims, the next determination is infringement. Accordingly, we must determine whether the court clearly erred in holding that the claims do not read on HibTITER. As stated above, the characteristics of HibTITER are undisputed. The only issue is whether the phrase "linkage to a terminal portion of the polysaccharide without significant crosslinking" reads on the HibTITER product as a whole, which, in view of NRC's concession at oral argument,<sup>3/</sup> requires determination whether the phrase reads on a product which includes dimers and trimers as well as monomers. In view of our decision that this phrase covers linkage at only one terminal portion of the polysaccharide and does not include end-to-end crosslinking, the HibTITER product including dimers and trimers clearly is not within the scope of the claims. Accordingly, the district court did not clearly err in concluding that HibTITER does not infringe claims 12 and 25.<sup>4/</sup>

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<sup>3/</sup> The dissent, in its commentary on claim 25, ignores the clear and unmistakable concession by NRC that it is not challenging the trial court's ruling that "conjugate" means the mixture of molecules as opposed to individual molecules. Whatever NRC's reasons, we do not review what it chooses to accept. Moreover, if claim 11 is not infringed, as we have concluded, dependent claim 25 cannot be.

<sup>4/</sup> The dissent argues at great length that the specification "reveals the inventors' intent" that cross-linking only means backbone cross-linking, and that "a terminal portion" includes two terminal portions. It refers to the specification's "clear meaning" and that it "clearly did not limit the claims." The plain fact, however, is that these matters are not clear at all and that  
(continued...)

### B. Validity

The district court concluded that claims 12 and 25 were invalid for indefiniteness under 35 U.S.C. § 112, second paragraph, which requires that the "specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." Even though we have affirmed the district court's decision of noninfringement, we find it desirable to review this holding of invalidity. See Cardinal Chem. Co. v. Morton Int'l. Inc., 113 S. Ct. 1967, 26 USPQ2d 1721 (1993). NRC is entitled to have the validity of its claims considered rather than have the district court's judgment merely vacated, leaving a cloud on the patent. Future modification of Cyanamid's product, or sale by another party, could raise questions of infringement of the claims as we and the district court have construed them. Finally, since we have thoroughly reviewed the case, no added judicial effort is involved.

The underlying basis for the court's conclusion of invalidity on the ground of indefiniteness was the parties' stipulation that the five categories of polysaccharides recited in claim 12, and the two categories recited in claim 25, each include a number of members (serotypes) which, when treated according to the teachings of the '170 patent, would result in polyfunctional molecules, polysaccharides having protein linkages along their backbones.

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<sup>4/</sup>(...continued)  
the specification contains no express disclosure of difunctional molecules.

This result is outside the scope of claim 11 and contrary to the teachings of the patent. On the basis of this fact, the court held the claims indefinite, stating that "there are so many different kinds of polysaccharides referred to which would yield different results, polyfunctional, difunctional and monofunctional, some of which results are admittedly contrary to the patent's teaching." 24 USPQ2d at 1903. NRC argues that the court's conclusion was erroneous. Specifically, NRC asserts that Cyanamid failed to meet its burden of proving that the claims are indefinite, and that the parties' stipulation was an insufficient basis for the court's holding that the claims are invalid. We agree with NRC that the parties' stipulation of possible inoperativeness of some species does not constitute an admission that those skilled in the art would not be reasonably apprised of the scope of the claims.

Under 35 U.S.C. § 282 (1988), a patent is presumed valid, and at trial Cyanamid had the burden of proving facts by clear and convincing evidence showing that the patent is invalid. See Buildex, Inc. v. Kason Indus., Inc., 849 F.2d 1461, 1463, 7 USPQ2d 1325, 1326-27 (Fed. Cir. 1988). Compliance with the definiteness requirement is a question of law which we review de novo. Carl Zeiss Stiftung v. Renishaw plc, 945 F.2d 1173, 1181, 20 USPQ2d 1094, 1101 (Fed. Cir. 1991). Whether a claim is invalid for indefiniteness depends on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the specification. Orthokinetics, Inc. v. Safety Travel Chairs,

Inc., 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986) (citations omitted).

Cyanamid did not meet its burden under the clear and convincing standard to show that one of ordinary skill would not understand what is included within claims 12 and 25. Claim 11, the claim from which claims 12 and 25 depend, requires linkage at a terminal portion of the polysaccharide. The specification is clear that the claimed invention relates to conjugates having a protein linkage at a single terminal portion of the polysaccharide, not at both terminal portions. Thus, while the parties in the midst of a dispute have disagreed concerning the meaning of the claims, the claims are not so lacking in clarity as to be invalid under section 112.

The categories of polysaccharides recited in claims 12 and 25 do include numerous members (serotypes), some of which apparently result in polyfunctional molecules when treated according to the teachings of the patent. The fact that dependent claims include species which might not meet the objects of the invention does not by itself prove that one skilled in the art cannot ascertain the scope of the asserted claims. That objection goes to possible inoperativeness under 35 U.S.C. § 101 or lack of enablement under 35 U.S.C. § 112, first paragraph, neither of which provisions are before us. Moreover, if a species within a dependent claim does not meet the limitations of the independent claim, arguably it is not included within the scope of that dependent claim.

The law is clear that "[i]f the claims, read in the light of the specification[s], reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more." Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir.), cert. dismissed, 474 U.S. 976 (1985) (quoting Georgia-Pacific Corp. v. United States Plywood Corp., 258 F.2d 124, 136, 118 USPQ 122, 132 (2d Cir.), cert. denied, 358 U.S. 884 (1958)). That is the case here.

NRC's expert, Dr. Schoolnik, testified on cross-examination that, in view of the teaching in the specification to avoid protein linkage along the backbone of the polysaccharide, he would know that the polysaccharides recited in claims 12 and 25 refer only to the serotypes that would result in "a clean backbone when the procedures recommended by [the] patent are performed on those structures." He testified:

[I]t's understood by everyone working in the field that you first draw out from [the group of bacterial types in claim 12] the particular types that are relevant to infantile meningitis, and then I think, as a scientist, I would look at the structure of the polysaccharides from those types and I would say are they structures that would, when subjected to this process, leave a backbone that's antigenic and probably, therefore, effective as a vaccine.

We conclude that the claims are sufficiently clear to apprise those skilled in the art of their scope. We thus reject

Cyanamid's argument that indefiniteness "follow[s] directly from stipulated facts," as that stipulation was insufficient as a matter of law to sustain the court's holding that claims 12 and 25 are indefinite. Accordingly, we conclude that the court erred in its holding of invalidity.

#### CONCLUSION

The court did not err in holding claims 12 and 25 of the '170 patent not infringed, but did err in holding them invalid. Accordingly, the judgment of the district court is affirmed-in-part and reversed-in-part.

#### COSTS

No costs.

**AFFIRMED-IN-PART AND REVERSED-IN-PART**

United States Court of Appeals for the Federal Circuit

93-1076

NORTH AMERICAN VACCINE, INC. and  
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Defendants-Appellees.

RADER, Circuit Judge, dissenting.

I agree with this panel that the district court erroneously concluded that claims 12 and 25 were invalid for indefiniteness. I also agree that the district court erred in relying on the inventors' scientific articles to determine the scope of the claims. Unfortunately, I cannot support the rest of this court's opinion.

As the panel points out, the district court erroneously based its decision on the inventors' articles in scientific journals. Although a patent specification may supply guidance about the meaning of claim terms, Hormone Research Foundation v. Genentech, Inc., 904 F.2d 1558, 1562, 15 USPQ2d 1039, 1043 (Fed. Cir. 1990), scientific literature differs in purpose, scope, and legal effect from patent writings. Because inventors generally have extraordinary skill, their scientific writings outside the patent are rarely even a source of knowledge about ordinary skill in the art. The panel's opinion correctly notes the trial court's error in relying extensively on the inventors' scientific articles for its claim interpretation. The trial court referred to the scientific writings as "the most important point in the evidence." Surprisingly, however,

the panel's opinion did not consider this error a cause for reversal. In a case the district court repeatedly characterized as "very close," this extensive reliance on impermissible evidence constitutes reversible error. Without the primary source of evidence upon which the district court based its decision, this "very close" case would no doubt have ended differently.

The majority suggests that the meaning of the term "conjugate" was conceded by North American Vaccine. In context, however, it appears that counsel was only trying to argue that the interpretation of the term "conjugate" is not dispositive. Moreover, plaintiff's reply brief actually contests the majority's interpretation and argues that the district court's ruling was incorrect. The majority hinges its conclusion on an equivocal statement made to pursue a more important concern. This approach appears unwarranted under the circumstances.

Claim 11 -- "at a terminal portion"

An examination of the claim language shows that the district court's use of impermissible evidence infected the judgment in this case. Claim 11 requires linkage of a protein "to a terminal portion of the polysaccharide." The accused product literally reads on this requirement. The panel's opinion and both parties concede: "The protein linkage in each of these components is at a terminal portion of the Hib polysaccharide . . . ." Slip Op. at 4, lines 8-10.

A branched polysaccharide, however, can have two or more terminal ends. The accused product linked protein at two of these

terminal ends. The trial court, relying on the inventors' scientific writings about "monofunctionality" or "monovalency" (technical terms for linkage at a single terminal end), interpreted the claim language to mean that any more than a single link at a terminal end escapes infringement.

The claim, however, does not require linkage "at a single terminal portion of the polysaccharide," but simply "at a terminal portion." The trial court used extraneous scientific writings to create a limitation -- at a single terminal portion -- not found in the claim language. Indeed in patent claims, the indefinite article "a" may denote one or more objects. Robert C. Faber, Landis on Mechanics of Patent Claim Drafting 531 (3d ed. 1990) ("In a claim, the indefinite article A or AN connotes 'one or more'").

Thus, according to the claim language, each link at a terminal portion of the polysaccharide reads on the claims. American Cyanamid infringed the patent by linking a protein to "a terminal portion" of the polysaccharide. When American Cyanamid linked a protein to two terminal ends, it still linked to "a terminal end" and infringed the claim. American Cyanamid indisputably always links at a terminal portion of the polysaccharide, but argues that the trial court correctly read "a terminal portion" to mean "a single terminal portion." The claims simply do not contain that limitation.

If the trial court had properly relied on the patent specification or prosecution history to construe the claims, it would have noted that these correct patent sources do not even mention "mono-

functionality" or "monovalency." A comparison of the inventors' scientific writings with their later patent writings shows a complete deletion of all references to "monofunctionality" or "monovalency." Ironically, the scientific writings, in the proper context of the patent, show that the inventors -- by deleting references to "monofunctionality" -- clearly did not limit the claims to linkage at a single terminal end.

The panel's opinion recognizes the trial court's error in its extensive reliance on impermissible evidence. Nonetheless the panel compounds the error by creating on its own the same limitation. The panel purports to find this limitation in the specification.

In the first place, this court of appeals prohibits importation of limitations from the specification into the claims. In re Lundberg, 244 F.2d 543, 548, 113 USPQ 530, 534 (CCPA 1957). The panel's belated discovery of a limitation to a "linkage at only one terminal portion" in the specification should still not influence its reading of the claims. Slip Op. at 9, lines 17-18.

To my eyes, however, the specification does not contain anything close to the "only one terminal portion" limitation. As already noted, the specification never refers, even obliquely, to monofunctionality, i.e., linkage to a single terminal end. The panel perceives this monofunctionality in the singular references to terminal linkages and in a single example in the specification.

The singular references in the specification are an effort to preserve grammatical accuracy, not create a limitation. The speci-

fication adopts the same grammatical number as the terms in the claims. Because the claims discuss each terminal end separately, the specification does the same. Naturally, therefore, the specification uses the singular number. The specification does not demonstrate monofunctionality; rather, good grammar.

The specification's example from the meningococcal group of polysaccharides also does not create a limitation missing from the claims. This example discussed one element only of the Markush groups of claims 12 and 25. Monofunctionality in a single member of the Markush group does not mean all members of the group can only produce a single linkage. By narrowly construing the example and importing that construction into the claim, the panel in effect limits the patent to a single example in the specification. This single example simply does not, and should not, limit the entire claim.

A specification can supply understanding of unclear claim terms, but should never trump the clear meaning of claim terms. E. I. Du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1443, 7 USPQ2d 1129, 1131 (Fed. Cir. 1988). Moreover a specification should have a clear and distinct message before it influences claim meaning at all. In this case, the panel exalts the specification -- without a single express reference to "monofunctionality" and without any unambiguous reference limiting linkages to a single terminal -- over the express meaning of claim terms.

Not only did American Cyanamid literally infringe by linking to "a terminal portion," it chose precisely the polysaccharide mentioned in dependent claims 12 and 25 -- the polysaccharide of H. influenza. Moreover, the trial court found that the H. influenza polysaccharide links at more than one terminal end. Therefore, these dependent claims show that claim 11's language embraced each protein link "at a terminal portion." Not only does American Cyanamid literally infringe claim 11, it does so with precisely the polysaccharide in claims 12 and 25.

Claim 11 -- "without significant cross-linking"

Claim 11 also contains the phrase "without significant cross-linking." The term "cross-linking" could apply to three types of bonds: (1) the covalent bond between the protein and the polysaccharide polymers, (2) any linkage randomly located on the polysaccharide, and (3) a linkage at "a terminal portion of the polysaccharide" in the presence of another linkage. The claims exclude from the term "cross-linking" the type (1) bond because the claims call such a bond simply a "linkage". The specification includes the type (2) bond within "cross-linking." The Background section of the patent indicates that these random linkages along the polysaccharide were a problem in the prior art which the invention cures. Neither the claims nor the specification include the type (3) bond, linkage at "a terminal portion of the polysaccharide," within the realm of "significant cross-linking." In fact, the conspicuous absence of the terms "monofunctional", "monovalent",

and their equivalents from the specification suggest that the type (3) bonds are not the "significant cross-links" which the invention sought to avoid.

Indisputably, the terms of the claim preclude the type (1) bond as the prohibited cross-link. The specification expressly discusses the random type (2) bonds as the cross-links which reduced the conjugant's benefit as an antigen in the prior art. The patent discussed "significant cross-linking" only in the context of avoiding the prior art problem with "many randomly activated functional groups . . . on the various polysaccharides leading to considerable cross-linking." See Col. 2, lines 14-18. The invention specifically sought to avoid this type of random cross-linking. For this reason the claim expressly forbid "significant cross-linking." Thus, according to the specification, the "significant cross-linking" prohibited by the claims refers to type (2) bonds.

Furthermore, the specification also points out that the invention permits a difference between reactivity along the group C polysaccharide chain and reactivity at a terminal end. See, Col. 5, lines 50-54. These interchain linkages -- the random type (2) bonds -- display less reactivity than linkage at terminal ends. The inventors further explain that the interchain 2--8 linkages of the group B polysaccharide are even less likely to react under the conditions of the invention. See, Col. 5, lines 54-59. By noting this distinction, the specification reveals the inventors' intent to avoid interchain cross-links. Inexplicably the panel overlooks

this additional evidence that the invention intended the "without significant cross-linking" limitation to mean type (2) interchain linkages, the inventors' term for linkages along the backbone of the polysaccharide.

In the face of this clear evidence of the meaning of "without significant cross-linking," the trial court found that the type (3) bond was the forbidden form of cross-link. Again the trial court's reliance on impermissible evidence caused this error. Based on this external evidence, the district court incorrectly decided that the claim embraced only monofunctional linkages.

The panel again embraces the decision reached by the trial court's clear error. In this case, however, the panel cannot draw credible support for its position from the specification. The patent specification clearly suggests that "without significant cross linking" refers to "many randomly activated functional groups" and not to cross-linking at a terminal portion of the polysaccharide.

More importantly, the panel overlooks the language of the claims. The claim language discusses linkage "at a terminal portion" specifically and then generally prohibits "significant cross-linking." The specific reference to terminal portion linkage suggests that the general cross-linking language refers to something other than terminal portion linkage. Striving to justify its importation of monovalency into the claim terms, the panel construes "cross-linking" as the type (3) bond. In doing so, however,

the panel disregards the language of the claims and the clear meaning of the specification.

#### Claim 25

Neither the trial court nor the panel adequately explains how the accused composition avoided infringement of claim 25. Even construing "without significant cross-linking" to mean "with absolutely no cross-linking," the accused product still infringes claim 25. Claim 25 uses open ended "comprising" terminology. The claim requires only that the vaccine contain a component which is (i) an H. influenza polysaccharide, (ii) antigenic with a molecular weight ( $M_v$ ) above 2,000, (iii) a polysaccharide:protein coupled via  $-CH_2-N$ -protein linkage to "a terminal portion of the polysaccharide," and (iv) "without significant cross-linking." American Cyanamid's accused product contains a component which the trial court called a "monomer." Dr. Eby, Cyanamid's own expert witness, testified that 50% of the accused product was this "monomer" component. Both parties agree and the district court found that this monomer component is a non-cross-linked species of protein linked to polysaccharide. Therefore, this component is (i) an H. influenza polysaccharide, (ii) antigenic with a  $M_v$  above 2,000, (iii) a polysaccharide:protein coupled via  $-CH_2-N$ -protein linkage to "a terminal portion of the polysaccharide," and (iv) "without significant cross-linking." By any definition, this product with 50% infringing material infringes the open-ended claim 25.

American Cyanamid merely took a patent on A,B,C -- (A) H. influenza polysaccharide (B) linked at a terminal portion to protein (C) without significant cross-linking -- and added a new element, D. The new element, D, is material ("dimers" and "trimers") linked at more than one terminal position. Adding some "dimers" to the infringing "monomer" material does not defeat infringement. Adding an additional component D does not defeat infringement of an open-ended claim to A,B,C. Loctite Corp. v. Ultraseal, Ltd., 781 F.2d 861, 865, 228 USPQ 90, 92 (Fed. Cir. 1985) ("It is uncontested that Ultraseal's PC504 contains a monomer and an initiator selected from the monomers and initiators of the patent claims. Though PC504 also includes components not required by the claims, such inclusion does not avoid infringement. . . .") (footnote omitted); Amstar Corp. v. Envirotech Corp., 730 F.2d 1476, 1484, 221 USPQ 649, 655 (Fed. Cir.), cert. denied, 469 U.S. 942 (1984); A.B. Dick Co. v. Burroughs Corp., 713 F.2d 700, 703, 218 USPQ 965, 967 (Fed. Cir. 1983), cert. denied, 464 U.S. 1042 (1984) ("It is fundamental that one cannot avoid infringement merely by adding elements if each element recited in the claims is found in the accused device").

Overlooking claim 25's language totally destroys the value of the patent. Potential infringers need only add an additional component, i.e., some "dimer" material, to avoid infringement. Thus, even adopting the trial court's strained interpretation of "conjugate", I would reverse the trial court's judgment of non-infringement on claim 25.

### Conclusion

This claim is not ambiguous. It clearly requires only linkage "at a terminal portion." Nonetheless the Supreme Court's admonition applies here: "if the claim [is] fairly susceptible of two constructions, that should be adopted which will secure to the patentee his actual invention." Smith v. Snow, 294 U.S. 1, 14 (1935). The record also shows American Cyanamid could not create "[a]n antigenic-polysaccharide:protein conjugate wherein the polysaccharide and protein are covalently linked through a CH<sub>2</sub>-N-protein linkage to a terminal portion of a polysaccharide," until shortly after gaining access to the inventors' work. In the face of evidentiary errors by the trial court in conflict with the meaning of the claims, I would remand.